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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,489	07/31/2001	Isabel Antonia Maria Van Waterschoot	01-468	9467

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,489	VAN WATERSCHOOT ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/23/2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' preliminary amendment, filed 07/31/2001; and IDS, filed 08/23/2001.

Specification

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

2. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

3. The use of the trademarks: "OPTIMAR", "EFALEX", "EFAMARNITE", "ARASCO", "DHASCO", "EPAX", "EFANATAL" have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for capsule or gelatin capsule for use as a dietary supplement for pregnant women and elderly patients, does not reasonably provide enablement for edible formulation or any other pharmaceutical compositions or for uses of the formulation other than dietary supplementation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the invention is composition comprising ARA by itself or in combination with and DHA and method of its use as dietary supplement for pregnant or lactating women or elderly patients; uses for assisting in the prophylaxis, preventing, ameliorating, or treating of schizophrenia, cystic fibrosis, idiopathic immunoglobin A neuropathy, multiple sclerosis, retinitis pigmentosis, Usher's syndrome, celiac disease, macular degeneration, Parkinsonians' disease, osteoporosis, Alzheimer's disease or phenylketonuria; use in person with abnormal immune level; or as promoter for reproductive and fertility efficiency or success. The nature of the invention is extremely complex in that it encompasses wide varieties of formulations comprising ARA and DHA used for prevention and treatment of multiple complex disorders having unrelated manifestations and etiology, and subsequently treated by administering the instant composition. The entire specification disclosed oral composition in form of capsule or gelatin capsule comprising ARA or combination of ARA and DHA used as dietary supplement for pregnant women and elderly patients, examples 1-6. Nowhere in the specification applicants disclosed formulations other than capsules, or uses other than dietary supplement. Further, the specification does not enable the prevention or treatment of any of the disorders as claimed in claims 16-24.

The breadth of the claims: The claims are very broad. The complex nature of the claims is exacerbated by the breadth of the claims. The claims encompass all verities of pharmaceutical compositions including oral, topical, parenteral or edible compositions. The claim encompasses prevention and treatment of complex disorders that may have potential causes other than those disclosed in the specification. This may

or may not be addressed by the administration of the instant composition. For example osteoporosis and infertility can be caused by hormonal disturbance and diabetes can be caused by pancreatic disorders. Moreover, the specification is directed to dietary supplement for pregnant and elderly patients, however, numerous other disorders, such as neurological diseases, abnormal immune level, and infertility disorders are encompassed by the instant claims. The claims further encompass prevention of neurological disorders and the burden of enabling prevention of neurological disorders would be greater than that of enabling a treatment due to the need of additional testing and screening to those humans susceptible to such disorders. The prevention of all the claimed neurological disorders, uses in persons with abnormal immune level and infertility treatment may or may not be addressed by the administration of the instant composition. Further, the claims encompass all the forms of the pharmaceutical composition.

The state of the prior art: The state of the art does not recognize the administration of compositions to prevent any of the claimed neurological disorders as required in the instant claims. The state of the art recognizes the treatment of neurological disorders, but not their cure.

The relative skill of those in the art: The relative skill of those in the art is high.

The amount of direction or guidance presented: The guidance given by the specification on how to prevent all the claimed disorders is absent. No evidence is provided that any of the neurological conditions, abnormal immune level or infertility is prevented or even treated. Guidance for a capsule used as dietary supplement is

provided. Furthermore, the specification provides no guidance, in the way written description, on any pharmaceutical compositions other than capsules. The specification provides guidance on oral capsule comprising DHA and/or ARA used as dietary supplement. It is not obvious from the disclosure of capsule comprising DHA and/or ARA used as a dietary supplement if other formulations for other uses will work. *In re Dreshfield*, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." The article "Broader than the Disclosure in Chemical Cases," 31 J.P.O.S. 5, by Samuel S. Levin covers this subject in detail. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The predictability or unpredictability of the art: The lack of significant guidance from the specification or prior art with regard to formulations other than capsule comprising ARA and DHA that completely prevent or even treat all the claimed neurological and fertility disorders and use in persons with abnormal immune level makes practicing the claimed invention unpredictable in terms of the using other formulations for treating and prevention of the neurological disorders, use in persons

with abnormal immune level and treatment of fertility disorders that may have causes other than fatty acid deficiency.

The presence or absence of working examples: The specification discloses only oral capsule comprising ARA and/or DHA used as dietary supplement for pregnant women and elderly patients, examples 1-6. No working examples to show formulations other than capsule, not even an edible formulation, used to treat or prevent any neurological disorders, used in persons with abnormal immune level or for treatment of fertility disorders as recited in the claims. Therefore, the specification has only enabled oral capsule comprising ARA and DHA as dietary supplement for pregnant and elderly patients.

The quantity of experimentation necessary: Therefor, the practitioner would turn to trial and error experimentation to practice the instant composition and method for treating and preventing all unrelated disorders that may have potential causes other than ARA and DHA deficiency without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 5, 12-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 5 recites the broad recitation ARA:DHA is from 1:5 to 5:1, and the claim also recites the ratio 1:1 which is the narrower statement of the range/limitation. Claim 12 recites the broad recitation of age from 40-60, and the claim also recites the ratio 50-55 which is the narrower statement of the range/limitation. Claim 13 recites the broad recitation ARA dose is from 150-700, and the claim also recites the ratio 250-500 mg/day which is the narrower statement of the range/limitation. Claim 17 recites the broad recitation neuronal disease, and the claim also recites schizophrenia, cystic fibrosis, idiopathic immunoglobin A neuropathy, multiple sclerosis, retinitis pigmentosis, Usher's syndrome, celiac disease, macular degeneration, Parkinsonians' disease, osteoporosis, Alzheimer's disease or phenylketonuria which are the narrower statement of the range/limitation.

Regarding claim 16, the claim recites the acronym "PUFA" which is not permitted in the claims.

Claims 12-24 provide for the use of ARA and DHA, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 12-24 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-6, 8-11, 16, 17, 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/37200 ('200).

WO '200 disclosed composition comprising DHA and ARA to be administered to patients suffering from retinal diseases (abstract; page 3, lines 8-42; page 6, claims 1-5). The composition is in the form of capsule or as food (page 4, lines 4-10, 14-18). The

ratio of DHA:ARA is 5:1 to 1:5, and the amount of DHA is from 1 mg to 100 g/day (page 6, claims 4, 8). The amount of ARA is calculated to be 0.2 mg to 500 g/day. The ARA forms 2% of the food formulation (page 5, lines 1-3).

10. Claims 1-6, 8-10, 16, 17, 19-24 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/40106 ('106).

WO '106 disclosed a method for treating neurological disorders including Alzheimer's disease, schizophrenia, diabetic patients, multiple sclerosis or phenylketonuria by administering a composition comprising ARA or ARA and DHA (abstract; page 6, lines 4-6, 20-28; page 7, lines 1-4; page 8, lines 9-11, 22-28page 70, lines 23-25). The formulation can be used as dietary supplement as food or any oral or topical formulation (page 28, lines 3, 11-14; page 29, lines 11-24). The dose of each of ARA and DHA is 50-5000 mg/day (page 30, lines 20-28). The daily dose is adjusted to maintain the circulating levels of ARA and DHA at the desirable level (page 31, lines 13-15). The formulation is in the form of capsule (page 42, lines 5-7). The ratio of DHA:ARA is 2:1 to 1:2 (page 42, lines 225-28; page 43, lines 8-11; page 71, lines 1-2).

11. Claims 1-3, 6, 8, 9, 16, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 409 559 ('559).

EP '559 disclosed a pharmaceutical and dietary uses of AA for treating alcoholism, diabetes, and systemic sclerosis (abstract; page 5, lines 5-18). The AA may be combined with DHA (page 5, lines 54-55). The AA and DHA are presented in form of

oral or ingestible liquid (page 7, lines 45-50). The formulations comprises 10 mg to 10 g/day of AA and (page 6, line 58).

12. Claims 1-6, 9, 10, 16, 17, 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 733 360 ('360).

EP '360 disclosed combination of ARA and DHA used at the ratio of 5:1 to 1:5 in a capsule form to treat schizophrenia (abstract; page 3, lines 54-46; page 4, line 34). The amount of ARA and DHA is from 200 mg to 1 g/ day (page 4, lines 23-35).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 7, 12-15, 18, 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '200.

The teachings of WO '200 are discussed under 102 rejection above.

WO '200 does not teach the formulation administered twice daily, or the uses of the composition for dietary supplement for pregnant women or elderly patients or uses in patients with abnormal immune level.

It is within the skill in the art to determine the profile of administration of a pharmaceutical formulation to achieve the desired effect. Thus, the claimed profile does not consider critical since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233. It is also within the skill in the art to use formulation comprising ARA and DHA to treat conditions or disorders known to be caused by the deficiency of these fatty acids.

16. Claims 7, 11-15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '106.

The teachings of WO '106 are discussed under 102 rejection above.

WO '106 does not teach the formulation administered twice daily, composition comprising 0.1-5% ARA, the uses of the composition for dietary supplement for pregnant women or elderly patients.

It is within the skill in the art to determine the profile of administration of a pharmaceutical formulation and the amount in order to achieve the desired effect. However, the reference suggests that the daily dose can be modified to maintain the circulating DHA and ARA at the desired level (page 31, lines 14-15), and also suggests the use of the DHA and/or ARA as a nutritional supplement (page 29, lines 10-13). The claimed profile and amount are not considered critical since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

17. Claims 4, 5, 7, 10-15, 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '559.

The teachings of EP '559 are discussed under 102 rejection above.

EP '559 does not teach the formulation administered twice daily, the amounts and ratio of different ingredient, the uses of the composition for dietary supplement for pregnant women or elderly patients.

It is within the skill in the art to determine the profile of administration of a pharmaceutical formulation and the amount in order to achieve the desired effect. Thus, the claimed amounts and ratios are not considered critical since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the

optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233. It is also within the skill in the art to use formulation comprising ARA and DHA to treat conditions or disorders known to be caused by the deficiency of these fatty acids.

18. Claims 7, 8, 11-15, 18, 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '360.

The teachings of EP '360 are discussed under 102 rejection above.

EP '360 does not teach the twice/day administration, the percentage of ARA in foodstuff formulation, the use of the formulation as nutritional supplement or use in persons with abnormal immune level.

It is within the skill in the art to determine the profile of administration of a pharmaceutical formulation and the amount in order to achieve the desired effect. Thus, the claimed percentage and profile of use are not considered critical since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233. It is also within the skill in the art to use formulation comprising ARA and DHA to treat conditions or disorders known to be caused by the deficiency of these fatty acids.

19. Claims 1, 2, 6-9, 12-15, 16, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/16119 ('119).

WO '119 teaches an edible formulation comprising ARA used for infant milk formulae and foods for pregnant and lactating mothers (abstract).

WO '119 does not teach the profile of administration of ARA or its amount. The amounts and profiles are not considered critical since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

20. Claims 3-5, 10,19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '119 in view of Makrides et al.

WO '119 teaches an edible formulation comprising ARA used for infant and foods for pregnant and lactating mothers (abstract).

WO '119 does not teach combining DHA with ARA.

Makrides et al. teach increases t he DHA in breast milk by dietary supplementation of DHA in amount 0.2-1.3 g/day.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to add DHA to the dietary composition comprising ARA for the pregnant or lactating women disclosed by WO '119, motivated by the teaching of Makrides et al. that DHA in the dietary supplement increases the DHA in the breast milk, with reasonable expectation of having a dietary supplement comprising all the needed fatty acids for the lactating mother and nursed infant.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

Isis Ghali

ISIS GHALI
PATENT EXAMINER